

Title: METHOD FOR MARKING, TRACKING, AND MANAGING  
HOSPITAL INSTRUMENTS

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## **BACKGROUND OF THE INVENTION**

### **1. Field of the Invention**

The present invention relates to a method for marking, tracking, and managing hospital instruments. Specifically, the present invention relates to a method for marking instruments with information indicative of the manufacturer, part number, serial number and manufacturing data of each instrument, inputting such information into a database, along with information regarding the desired maintenance schedule, and usage of each instrument, and tracking the usage and/or maintenance of each instrument by using the information in the database. The method also includes asset management, instrumentation identification and counting, and assembly of surgical trays and kits.

### **2. Description of the Prior Art**

It is extremely important to monitor and/or track the use of hospital instruments, particularly instruments used to perform surgery. Large hospitals often comprise many different departments. This multidepartment organizational structure frequently results in nonuniform, rather than centralized, attempts to track the maintenance and/or usage of hospital instruments.

Hospital instruments are expensive and often have short or limited useful lifetimes. The term "hospital instrument", as used herein refers to any

instrument or device used for patient care, diagnosis, therapy, or surgery in a hospital or in the office of a physician or surgeon. By way of example, hospital instruments may include, but are not limited to, defibrillators, ultrasonography transducers, and surgical instruments such as forceps. The term "hospital procedure", as used herein, refers to any procedure performed in a hospital or in the office of a physician or surgeon, using a hospital instrument. By way of example, hospital procedures include, but are not limited to, surgery, defibrillation, ultrasound imaging, and magnetic resonance imaging. The costs associated with maintaining and/or replacing hospital instruments are relatively high.

The lack of a centralized system for marking, tracking, and managing hospital instruments can result in unnecessary replacement costs, higher than necessary inventory levels, the failure to perform needed maintenance in a timely manner, or increased exposure to liability resulting from insufficient documentation of maintenance practices. The present invention overcomes the drawbacks of the prior art by providing a centralized system and/or method for marking, tracking, and managing hospital instruments.

Other prior art methods for marking surgical instruments require two separate marking techniques, one technique for surgical instruments having a mirror finish and a second technique for surgical instruments having a nonmirror finish. Such a method is disclosed in U.S. Patent No. 5,637,850 to Honda. Such dual marking methods are expensive in that they require complex hardware and software capable of distinguishing between the two different types of marking techniques used for different finishes on surgical instruments.

The present invention provides a great advantage over such prior art methods in that a single marking technique is used, regardless of the finish on a hospital instrument. This single marking technique provides economy, not only in the hardware used to mark the hospital instruments, but also in the hardware and software used to read the marks.

### **SUMMARY OF THE INVENTION**

The present invention is directed toward a method for marking and tracking a multiplicity of hospital instruments. This method comprises marking at least two hospital instruments with an optically scannable mark indicative of each instrument's manufacturer or service provider and indicative of a serial number unique to each instrument. The invention also comprises reading each mark and entering serial number and manufacturer information represented by each mark into a computer database. The invention further comprises using one or more of the instruments to perform one or more hospital procedures and entering information into the database that identifies each hospital procedure in which each instrument has been used.

The present invention may also be used to identify the sterilization and maintenance on each hospital instrument, identify instrument replacement as required or performed, conduct training, and/or identify the number of usages, repairs, and/or complaints associated with each instrument.

### **DESCRIPTION OF THE DRAWINGS**

Figure 1 is a block diagram of a first embodiment of the present invention.

Figure 2 is a block diagram of a second embodiment of the present invention.

Figure 3 is a block diagram of a system suitable for practicing the methods of the present invention.

Figure 4a is a side view of the marking step of the present invention.

Figure 4b is a side view of the scanning and entering step of the present invention.

Figures 5a–5b are a block diagram of a third embodiment of the present invention.

### **DESCRIPTION OF THE PREFERRED EMBODIMENTS**

A first embodiment of the present invention is directed toward a method for marking and tracking a multiplicity of hospital instruments. This embodiment comprises marking at least two hospital instruments with an optically scannable mark 35 indicative of each instrument's manufacturer and indicative of a serial number unique to each instrument, as shown in Block 10 of Figure 1 and in Figure 4a. In a preferred embodiment, the marking is performed with a laser 36, as shown in Figure 4a.

A suitable method for laser marking is laser etching. Laser etching can be used to mark coatings applied to the substrate of a hospital instrument. Pigments may be added to coatings on a hospital instrument in order to effect a color change when the pigments are subjected to a laser in the laser etching process. Suitable pigments for laser etching are available from Infosight Corporation of Chillicothe, Ohio.

Laser bonding is also a suitable method for laser marking many hospital instruments. Laser bonding is a process which involves the bonding of a material to a substrate surface using the heat generated by a laser. Pigments suitable for use with laser bonding are available from Cerdec Corporation of Washington, Pennsylvania. In other preferred embodiments, the marking is performed using an ink jet or an acid etch.

The laser marking technique may be laser etching, laser alloying or a combination of laser alloying and laser etching. Laser alloying may be

accomplished by coating the selected surface of the hospital instrument to be marked with a thin layer of precursor comprising metallic or ceramic elements suspended in a binder. The precursor coated instrument is then irradiated with a laser in a preselected pattern to form a patterned alloyed surface layer on the instrument. The selection of precursor elements will be a function of the chemical and/or materials composition of the hospital instrument. Alternatively, a selected surface area of the instrument may be irradiated to form a regional alloyed layer or apron. Other marking techniques, such as laser etching, may then be applied to the apron to produce a highly visible and wear resistant mark.

This embodiment of the invention further comprises reading each mark and entering serial number and manufacturer information represented by each mark into a computer database as shown in Block 12 of Figure 1 and in Figure 4b.

In a preferred embodiment, the reading and entering comprises scanning with an optical scanner electrically coupled to the database. The optical scanner automatically cycles through various lighting schemes and lenses to optimize the image capture. A suitable scanner for use in practicing the present invention is the RVSI MX-1 Handheld Reader, available from RVSI of Canton, MA.

In another preferred embodiment, the optical scanner is portable, as shown in Figure 4b. The electrical coupling provides a data transfer path or link between the scanner and the database. The data may also be transferred from the scanner to the database via infrared data transmission methods well known in the art, including Infrared Data Association (IrDA) standards. Other methods of wireless data transfer known in the data communications arts may also be employed in practicing the data entry step of the present invention,

including but not limited to RF methods. Other methods of data entry may include voice recordation or terminal entry.

In a preferred embodiment, the database is a relational database. The term "relational database", as used herein, encompasses a database comprising multiple entries, wherein each entry comprises multiple fields of information. In the context of the present invention, it is envisioned that entries will be specific to each instrument. The fields of information on each entry may include manufacturer, part number, serial number, usage history, and/or maintenance history.

In a relational database, information can be stored, sorted, and/or received based upon specified relations between various fields for each entry. For instance, in a relational database for the present invention it will be possible to retrieve entries on all instruments from a specified manufacturer, used in a specific hospital procedure within a specified time period. Such search and retrieval capabilities will facilitate using the present invention to audit instrument maintenance programs. A suitable relational database for use in practicing the present invention is DeRoyal's Meridian Instrument Control System and Pathways Management Module. Another relational database suitable for use in practicing the present invention is the Access database available from Microsoft Corporation of Redmond, Washington.

In a preferred embodiment, the database is accessible at multiple data entry and retrieval locations or data terminals 42, as shown in Figure 3. In another preferred embodiment, the database is accessible in a computer network. The data terminals 42, shown in Figure 3 may also be computers. In such an embodiment, Figure 3 illustrates a simplified computer network.

This embodiment of the invention further comprises using one or more of the instruments to perform one or more hospital procedures, as shown in Block 14 of Figure 1. This embodiment of the invention further comprises entering information into the database that identifies each hospital procedure in which each instrument has been used, as shown in Block 16 of Figure 1.

A second embodiment of the present invention is shown in Figure 2. This embodiment is directed toward a method for marking, tracking, and maintaining a multiplicity of hospital instruments.

It comprises marking at least two hospital instruments with an optically scannable mark indicative of each instrument's manufacturer or service provider and part number, and indicative of a serial number unique to each instrument, as shown in Block 20 of Figure 2. The term "part number", as used herein, refers to a number unique to each species or type of instrument, such as each trocar or each scalpel. The part number may be used to designate instruments for specified groupings, such as groups of instruments for surgical or hospital kits.

This embodiment of the present invention also comprises reading each mark and entering part number, serial number, and manufacturer or service provider information conveyed by each mark into a computer database, as shown in Block 21 of Figure 2. In another preferred embodiment, the reading and entering is performed with a portable optical scanner 38 electrically coupled to the computer database, as shown in Figures 3 and 4b. The present invention may also be used to scan groups of instruments that are placed in a kit or to identify instruments for sorting into kits. The kit may also be marked, scanned and tracked using the present invention.

This embodiment of the present invention further comprises using one or more of the instruments to perform one or more hospital procedures as shown in Block **22** of Figure 2, and entering information into the database that identifies the serial number of each instrument and each hospital procedure in which it has been used, as shown in Block **23** of Figure 2. Hospital procedure information may include an identification of the specific procedure, when it was performed, the nurses/technicians assigned to the procedure, and the surgeons who performed it.

This embodiment of the present invention further comprises inputting a maintenance schedule for each instrument into the database as shown in Block **24** of Figure 2 and retrieving maintenance schedule information from the database as shown in Block **26** of Figure 2.

In a preferred embodiment, the retrieving is performed at a data terminal **42** electrically coupled to the database **40**, as shown in Figure 3. The data terminal may be remotely located from the database. The terminal and database may be located in different buildings or in different rooms of the same building.

This embodiment further comprises performing maintenance on each instrument according to the maintenance schedule entered into the database, as shown in Block **28** of Figure 2. In a preferred embodiment, the invention further comprises entering information into the database identifying the maintenance procedure performed on each instrument, as shown in Block **30** of Figure 2.

A third embodiment of the present invention is directed toward a method for marking, tracking, and maintaining a multiplicity of hospital instruments and for auditing instrument maintenance. The invention may also

be used for determining and tracking replacement requirements and ordering information related to instruments. Such information is particularly useful to a hospital's procurement, or a physician's/surgeon's procurement, office or department. The present invention allows for the selective retrieval of information relevant to determining what replacement instruments should be ordered.

This embodiment is depicted in Figures 5a–5b. This method comprises marking at least two hospital instruments with an optically scannable mark indicative of each instrument's manufacturer or service provider and part number, and indicative of a serial number unique to each instrument, as shown in Block **70** of Figure 5a. The invention further comprises reading each mark with an optical scanner, and transmitting part number, serial number and manufacturer information conveyed by each mark from the scanner to a computer database, as shown in Blocks **71** and **72** of Figure 5a.

The invention further comprises using one or more of the instruments to perform one or more hospital procedures, and entering information into the database that identifies the serial number of each instrument and each hospital procedure in which it has been used, as shown in Block **73** and **74** of Figure 5a.

The invention further comprises inputting a maintenance schedule for each instrument into a database, and retrieving maintenance schedule information from the database, as shown in Blocks **75** and **76** of Figure 5b.

The invention further comprises performing maintenance on one or more of the instruments, and entering information into the database identifying the maintenance procedure performed on each instrument, as shown in Blocks **77** and **78** of Figure 5b.

The invention also comprises retrieving maintenance history and schedule information on one or more instruments and determining whether scheduled maintenance has been performed in a timely manner on the instruments, as shown in Block 79 in Figure 5b. This retrieval may take place from a data terminal capable of transmitting data to and receiving data from the database. The terminal may be remotely located from the database and coupled to the database via various data retrieval and/or transfer mechanisms, including, but not limited to, a telephone line 55 or a wireless telecommunication connection comprising a wireless modem, as shown in Figure 3. This step of the invention provides a mechanism for auditing compliance with the scheduled maintenance program.

The determination of whether scheduled maintenance has been performed in a timely manner can be accomplished by comparing the maintenance schedule for a particular instrument to the maintenance history for the same instrument. The use of a relational database can facilitate the selective retrieval of information for such a comparison.

The foregoing disclosure and description of the invention are illustrative and explanatory. Various changes in the size, shape, and materials, as well as in the details of the illustrative embodiments may be made without departing from the spirit of the invention.

WHAT IS CLAIMED IS:

- 1        1.     A method for marking and tracking a multiplicity of hospital instruments  
2           comprising:  
3           a.     marking at least 2 hospital instruments with an optically  
4                scannable mark indicative of each instrument's manufacturer or  
5                service provider and indicative of a serial number unique to each  
6                instrument;  
7           b.     reading each mark and entering serial number and manufacturer  
8                information represented by each mark into a computer database;  
9           c.     using one or more of the instruments to perform one or more  
10                hospital procedures; and  
11           d.     entering information into the database that identifies each  
12                hospital procedure in which each instrument has been used.
- 1        2.     The method of claim 1, wherein said marking is performed with a laser,  
2           an ink jet, or an acid etch.
- 1        3.     The method of claim 1, wherein said reading and entering comprises  
2           scanning with an optical scanner electrically coupled to the database.
- 1        4.     The method of claim 3, wherein the optical scanner is portable.
- 1        5.     The method of claim 1, wherein each of the scannable marks further  
2           comprises information indicative of the part number of each instrument.

- 1 6. The method of claim 5, further comprising inputting a maintenance  
2 schedule for each instrument into the database.
- 1 7. The method of claim 6, further comprising retrieving maintenance  
2 schedule information from the database, and performing maintenance  
3 on each of said instruments according to the maintenance schedule  
4 entered into the database.
- 1 8. The method of claim 7, further comprising entering information into the  
2 database identifying the maintenance procedure performed on each  
3 instrument.
- 1 9. The method of claim 1, further comprising entering information into said  
2 database specifying the maximum number of permitted uses for each  
3 instrument.
- 1 10. The method of claim 1, wherein the database is a relational database.
- 1 11. The method of claim 1, wherein the database is accessible at multiple  
2 data entry and retrieval locations.
- 1 12. The method of claim 11, wherein the database is accessible in a  
2 computer network.
- 1 13. A method for marking, tracking and maintaining a multiplicity of hospital  
2 instruments comprising:

- 3 a. marking at least 2 hospital instruments with an optically
- 4 scannable mark indicative of each instrument's manufacturer or
- 5 service provider and part number, and indicative of a serial
- 6 number unique to each instrument;
- 7 b. reading each mark and entering part number, serial number and
- 8 manufacturer information conveyed by each mark into a
- 9 computer database;
- 10 c. using one or more of the instruments to perform one or more
- 11 hospital procedures;
- 12 d. entering information into the database that identifies the serial
- 13 number of each instrument and each hospital procedure in which
- 14 it has been used;
- 15 e. inputting a maintenance schedule for each instrument into the
- 16 database;
- 17 f. retrieving maintenance schedule information from the database;
- 18 and
- 19 g. performing maintenance on each of the instruments according to
- 20 the maintenance schedule entered into the database.

1        15.    The method of claim 13, wherein said part number is indicative of  
2        designated instrument groupings.

17. A method for marking, tracking and maintaining a multiplicity of hospital instruments and for auditing instrument maintenance comprising:
- a. marking at least 2 hospital instruments with an optically scannable mark indicative of each instrument's manufacturer and part number, and indicative of a serial number unique to each instrument;
  - b. reading each mark with an optical scanner;
  - c. transmitting part number, serial number and manufacturer information conveyed by each mark from the scanner to a computer database;
  - d. using one or more of the instruments to perform one or more hospital procedures;
  - e. entering information into the database that identifies the serial number of each instrument and each hospital procedure in which it has been used;
  - f. inputting a maintenance schedule for each instrument into the database;
  - g. retrieving maintenance schedule information from the database;
  - h. performing maintenance on one or more of the instruments;
  - i. entering information into the database identifying the maintenance procedure performed on each instrument; and
  - j. retrieving maintenance history and schedule information for one or more instruments and determining whether scheduled

1 maintenance has been performed in a timely manner on the  
2 instruments or whether the instrument should be replaced.

1 18. The method of claim 17 wherein said determining comprises comparing  
2 the maintenance schedule for a particular instrument to the  
3 maintenance history for the same instrument.

4 19. The method of claim 17 wherein said database contains information  
5 regarding the maximum number of permitted uses for each instrument  
6 and said determining comprises comparing the maximum number of  
7 permitted uses for a particular instrument to the usage history for the  
8 same instrument.

1 20. The method of claim 17, wherein said retrieving is performed from a  
2 data terminal remotely located from the database.

## ABSTRACT

The present invention relates to a method for marking, tracking, and managing hospital instruments. Specifically, the present invention relates to a method for marking instruments with information indicative of the manufacturer, part number, and serial number of each instrument, inputting such information into a database, inputting information into the database regarding the desired maintenance schedule for each instrument, inputting information into the database regarding the usage of each instrument, and tracking the usage and/or maintenance of each instrument by using the information in the database. The method also includes asset management, instrumentation identification and counting, and assembly of surgical trays and kits.

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MARKING AT LEAST 2 HOSPITAL INSTRUMENTS WITH AN OPTICALLY SCANNABLE MARK INDICATIVE OF EACH INSTRUMENT'S MANUFACTURER OR SERVICE PROVIDER AND INDICATIVE OF A SERIAL NUMBER UNIQUE TO EACH INSTRUMENT;



12

READING EACH MARK AND ENTERING SERIAL NUMBER AND MANUFACTURER INFORMATION REPRESENTED BY EACH MARK INTO A COMPUTER DATABASE;



14

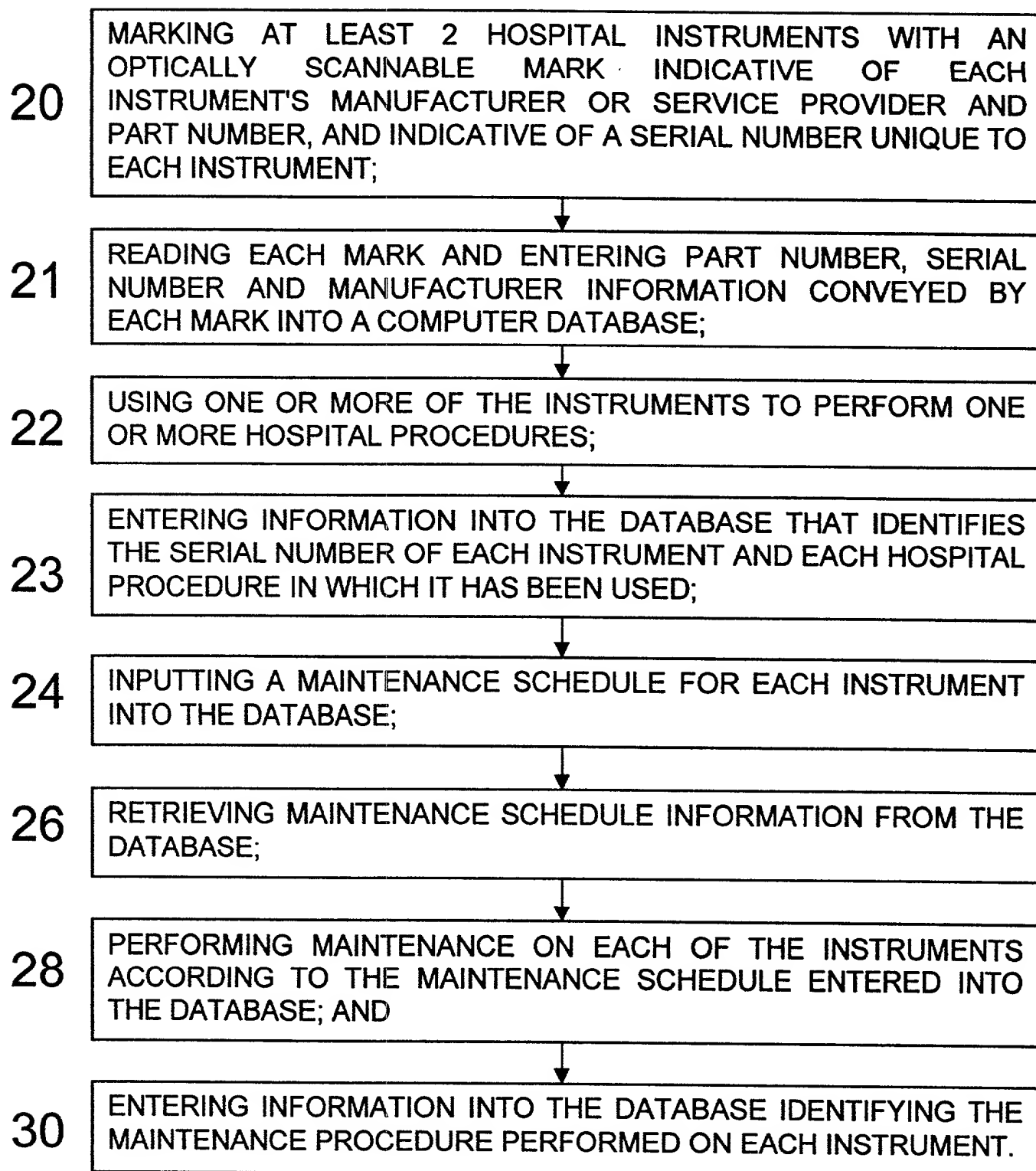
USING ONE OR MORE OF THE INSTRUMENTS TO PERFORM ONE OR MORE HOSPITAL PROCEDURES; AND



16

ENTERING INFORMATION INTO THE DATABASE THAT IDENTIFIES EACH HOSPITAL PROCEDURE IN WHICH EACH INSTRUMENT HAS BEEN USED.

*Figure 1*



*Figure 2*

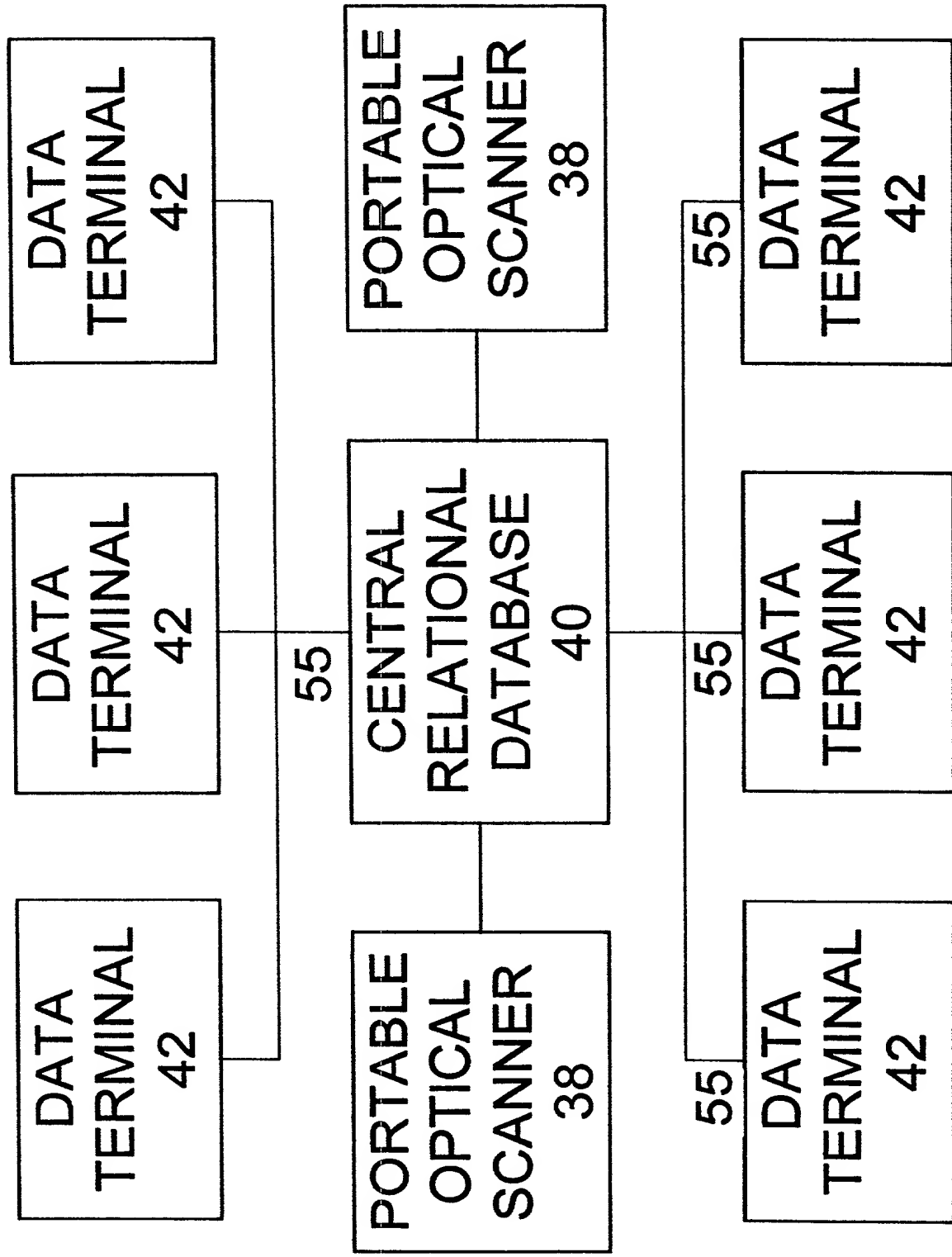
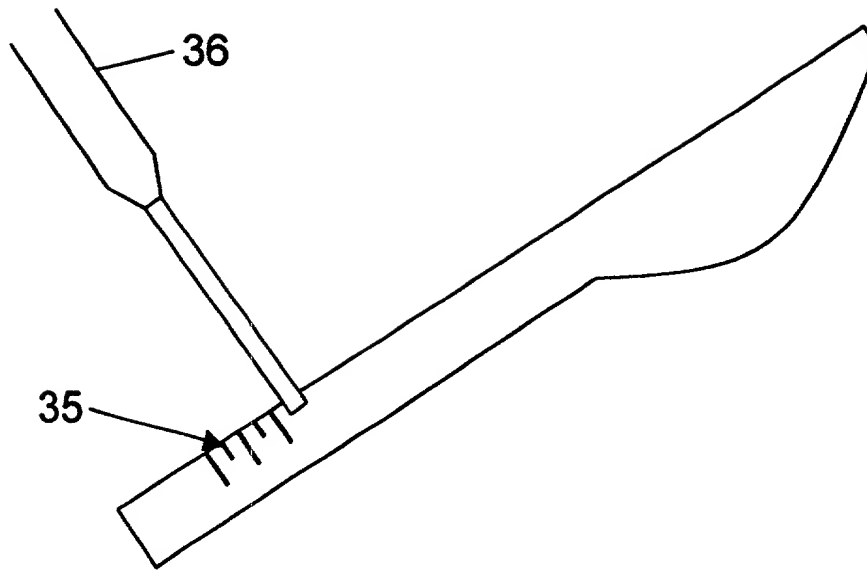
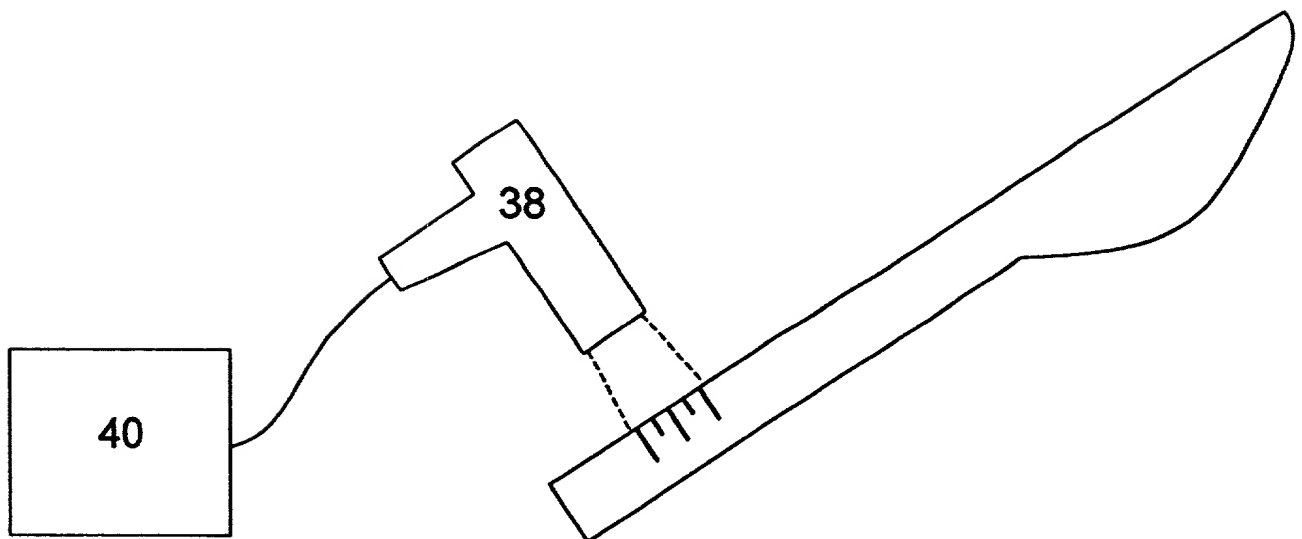


Figure 3



*Figure 4a*



*Figure 4b*

70

MARKING AT LEAST 2 HOSPITAL INSTRUMENTS WITH AN OPTICALLY SCANNABLE MARK INDICATIVE OF EACH INSTRUMENT'S MANUFACTURER OR SERVICE PROVIDER AND PART NUMBER, AND INDICATIVE OF A SERIAL NUMBER UNIQUE TO EACH INSTRUMENT;

71

READING EACH MARK WITH AN OPTICAL SCANNER;

72

TRANSMITTING PART NUMBER, SERIAL NUMBER AND MANUFACTURER INFORMATION CONVEYED BY EACH MARK FROM THE SCANNER TO A COMPUTER DATABASE;

73

USING ONE OR MORE OF THE INSTRUMENTS TO PERFORM ONE OR MORE HOSPITAL PROCEDURES;

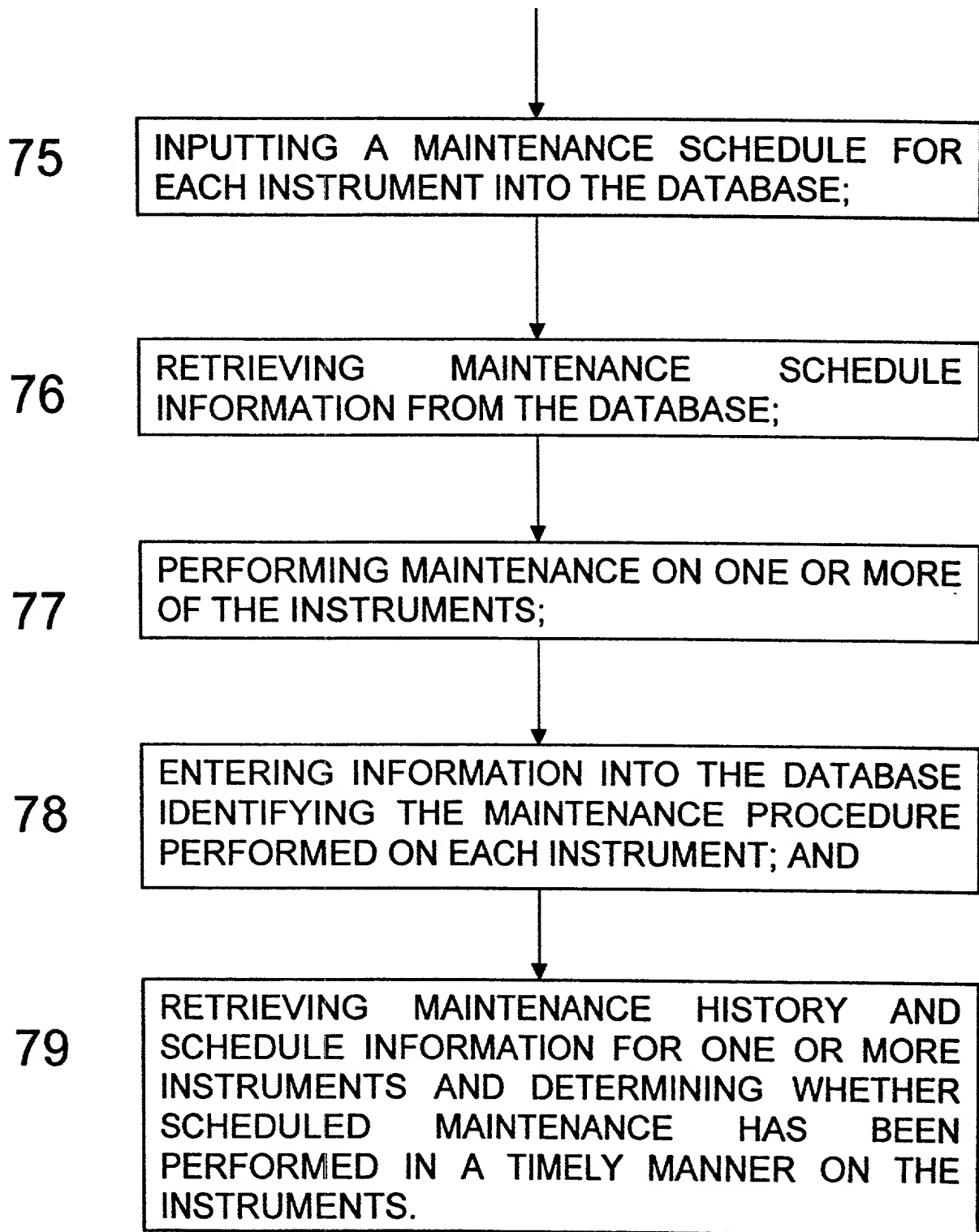
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ENTERING INFORMATION INTO THE DATABASE THAT IDENTIFIES THE SERIAL NUMBER OF EACH INSTRUMENT AND EACH HOSPITAL PROCEDURE IN WHICH IT HAS BEEN USED;

CONTINUED ON FIGURE 5b

*Figure 5a*

CONTINUED FROM FIGURE 5a



*Figure 5b*

**DECLARATION**

As the below named inventors, we hereby declare that:

Our residences, post office addresses, and citizenship are as stated below.

We believe we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled: **Method for Marking, Tracking, and Managing Hospital Instruments**, the specification of which is attached hereto.

We hereby state that we have reviewed and understand the contents of the above identified specification, including the claims.

We acknowledge the duty to disclose to the Office all information which is material to patentability as defined in 37 C.F.R. § 1.56.

We hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

**PRIORITY CLAIMED**NONE

(Number)

(Country)

(Date filed)

We hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112. We acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56, regarding events which occurred between the filing date of any such prior application and the national or PCT International filing date of this application:

(Application Serial No.)

(Filing Date)

(Status)

NONE

We hereby direct that all correspondence and telephone calls be addressed to Richard T. Redano, ROSENBLATT & REDANO, P.C., One Greenway Plaza, Suite 500, Houston, Texas 77046, Telephone: (713) 552-9900; Facsimile: (713) 552-0109.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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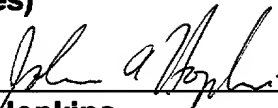
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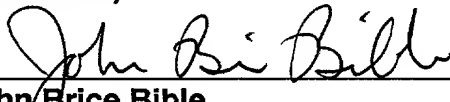
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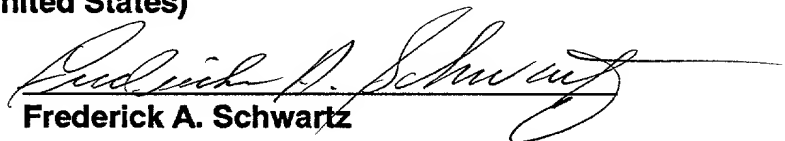
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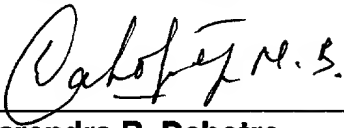
March 22, 1999  
Date

  
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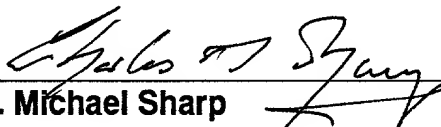
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Date

  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mary Helen McCay, et al.	§	
		§	
Serial No.:	Unknown	§	
		§	
Filed:	Herewith	§	
		§	
Title:	Method for Marking, Tracking, and	§	Docket: UTRC-57
	Managing Hospital Instruments	§	

Assistant Commissioner for Patents  
Washington, D.C. 20231

POWER OF ATTORNEY BY ASSIGNEE


As assignee of record of a portion of the entire interest of the above-identified application, I hereby appoint the following attorneys and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Richard T. Redano	Reg. No. 32,292
Steve Rosenblatt	Reg. No. 30,799

Please direct all correspondence to: **Richard T. Redano, Rosenblatt & Redano, P.C., One Greenway Plaza, Suite 500, Houston, Texas, 77046.** Direct telephone calls to: **Richard T. Redano at (713) 552-9900.**

**THE UNIVERSITY OF TENNESSEE  
RESEARCH CORPORATION**

3-17-99  
Date

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**Knoxville, Tennessee 37996-1527**

03/25/99  
1c648 U.S. PTO

A  
Docket No. UTRC-57

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of **Mary Helen McCay, T. Dwayne McCay, John A. Hopkins, John Brice Bible, Frederick A. Schwartz, Narendra B. Dahotre and C. Michael Sharp**, for their invention entitled: **Method for Marking, Tracking, and Managing Hospital Instruments.**

1. Papers enclosed which are required for filing date under 37 CFR 1.53(b):

10 Pages of specification  
05 Pages of claims  
01 Pages of abstract  
06 Sheet of drawing (in triplicate)

JC542 U.S. PTO  
09/276253  
03/25/99

2. Enclosed are the following documents in connection with this application:

Declaration  
Assignment, PTO-1595  
Power of Attorney  
Verified Statement Claiming Small Entity Status  
Information Disclosure Statement, PTO-1449, References Cited

3. The application is in the English language.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on **March 25, 1999**, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EL265782695US** addressed to the Assistant Commissioner of Patents, Washington, D. C. 20231.

Tracie Thigpen  
Tracie Thigpen

4. The fee calculation for a regular application is as follows:

CLAIMS AS FILED

	Number Filed				Number Extra		Rate		Basic Fee (37 C.F.R. 1.16(a) \$380
Total Claims	20	-	20	0	0	x	\$9	=	0
Independent Claims	3	-	3	=	0	x	\$39	=	0
Multiple Dependent Claims (if any)						+	\$130		
Total Filing Fee									\$380

5. Enclosed is a check in the amount of \$420 for the filing fee and the assignment recordation.
6. The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Deposit Account No. 18-2020.

37 CFR 1.16 (filing fees)

37 CFR 1.16 (presentation of extra claims)

37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application).

37 CFR 1.17 (application processing fees)

7. Any overpayment is to be credited to Account No. 18-2020.

Respectfully submitted,

ROSENBLATT & REDANO, P.C.

March 25, 1999

*Richard T. Redano*

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**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 CFR 1.9(f) and 1.27(c)) – SMALL BUSINESS CONCERN**

I hereby declare that I am an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Concern: The University of Tennessee Research Corporation

Address of Concern: 1534 White Avenue, Suite 403  
Knoxville, Tennessee 37996-1527

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 C.F.R. 121.3-18, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Sections 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third-party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to, and remain with, the small business concern identified above with regard to the invention, entitled:

**METHOD FOR MARKING, TRACKING AND MANAGING HOSPITAL  
INSTRUMENTS**

by inventors:

**MARY HELEN McCAY, T. DWAYNE McCAY, JOHN HOPKINS, JOHN  
BRICE BIBLE, FREDERICK A. SCHWARTZ, NARENDRA B. DAHOTRE,  
AND C. MICHAEL SHARP**

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 C.F.R. 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

NONE

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small business entity is no longer appropriate. (37 C.F.R. 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing:

Ann J. Roberson, Esq.

Title of Person:

President

Address:

1534 White Avenue, Suite 403  
Knoxville, Tennessee 37996-1527

3-17-99  
Date

Ann J. Roberson  
Signature

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